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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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WHITE & CASE
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER

FAN, J

ART UNIT	PAPER NUMBER
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1612

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DATE MAILED:

01/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/419,456

Applicant(s)
Lindberg et al.

Examiner
Jane Fan

Group Art Unit
1612



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 35-51 is/are pending in the application.

Of the above, claim(s) 51 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 35-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/256,174.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6,7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim 51 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim is not been further treated on the merits.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4,035,455 in view of CA 117:90292.

DE 4,035,455 at page 9, lines 31-32 teaches basic salts of (-)-5-methoxy-2-(94-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl-1H-benzimidazoles. CA 117:90292 specifically teaches the particular Na, K and Li basic salts. The pharmaceutical formulation derived from the compounds is taught in DE 4,035,455, page 13, line 12. A person skilled in the art would be motivated to make optically pure omeprazole as taught in DE 4,035,455 into a basic salt as taught in CA 117: 90292 and make the particular pure salts into a pharmaceutical formulation for inhibiting gastric acid secretion.

The declaration by Dr. Andersson has been carefully considered, but are not convincing for the following reasons:

1. The showing having Na salt in sterile solution by intravenous injection is not commensurate in scope with the claims wherein various alkaline salts for parenteral use is claimed.

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2. The declaration by Dr. Andersson showed (-)-enantiomer of omeprazole exhibit better activity than the racemate. However, this is just what would have expected since stereo isomers of a pharmaceutical compound do exhibit different activities. Difference in activity would have been expected.

3. It is only when the greater effectiveness would not have been expected that it may constitute a basis for patentability. If the beneficial results shown for a compound would have been expected, said results are evidence of obviousness, rather than unobviousness. *In re* Gershon, 54 CCPA 1066, 372 F.2d 535, 152 USPQ 602 (1967); *In re* Skoll, 523 F.2d 1392, 187 USPQ 481 (CCPA 1975); *In re* Hoffman, 556 F.2d 539, 194 USPQ 126 (CCPA 1977).

4. Applicants in their remarks stating that Cairns et al. teaches (+), (-) -enantiomer of omeprazole and racemate all have the same activity. Applicants are requested to point out and underline the pertinent portion of this statement in the reference and also the date (instant application's earliest priority of the claimed subject matter).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 35-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,900,424, 5,877,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because composition containing known compounds are unpatentable.

Claims 35-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/187,277. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42, 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claims are improper since they fail to recite a host for which the method is being administered.

TD submitted on November 15, 1999 has been considered and it is proper. The double patenting rejection over pat, 504 has been overcome.

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Other rejections in the parent file 08/899,931 have been overcome by applicants' remarks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANE FAN whose telephone number is (703) 308-4705.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JTF January 27, 2000



**JANE FAN
PRIMARY EXAMINER
GROUP 1200**